CDRH—contact David M. Whipple (HFZ–460), address above. The labeling of the SGP 3™ (unifocon A) Rigid Gas Permeable Contact Lens for Daily Wear (clear, blue, and green tinted) states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 1, 1991, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 22, 1991.

Elizabeth D. Jacobson,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. 91–7514 Filed 3–29–91; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 91P–0075]

Cottage Cheese Deviating From Standard of Identity; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Bison Foods Co., to market test a product designated as "nonfat cottage cheese" that deviates from the U.S. standards of identity for cottage cheese (21 CFR 133.128), dry curd cottage cheese (21 CFR 133.129), and lowfat cottage cheese (21 CFR 133.131). The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 1, 1991.

FOR FURTHER INFORMATION CONTACT:

Frederick E. Boland, Center for Food Safety and Applied Nutrition (HFF–414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0117.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Bison Foods Co., 196 Scott St., Buffalo, NY 14204.

The permit covers limited interstate marketing tests of a nonfat cottage cheese, formulated from dry curd cottage cheese and a dressing, such that the finished product contains from 0.1 to 0.3 percent milkfat. The food deviates from the U.S. standards of identity for cottage cheese (21 CFR 133.128) and lowfat cottage cheese (21 CFR 133.131) in that the milkfat content of cottage cheese is not less than 4.0 percent, and that the milkfat content of lowfat cottage cheese ranges from 0.5 to 2.0 percent. The test product also deviates from the U.S. standard of identity for dry curd cottage cheese (21 CFR 133.129) because of the added dressing. The test product meets all requirements of the standards with the exception of these deviations. The purpose of the variation is to offer the consumer a product that is nutritionally equivalent to cottage cheese products with dressing but contains less fat.

For the purpose of this permit, the name of the product is "nonfat cottage cheese." The information panel of the label will bear nutrition labeling in accordance with 21 CFR 101.9.

This permit provides for the temporary marketing of 500,000 pounds (226,800 kilograms) in 454-gram (16-ounce) containers of the test product. The product will be manufactured at Bison Foods Co., Division of Upstate Milk Cooperatives, Inc., 196 Scott St., Buffalo, NY 14204, and distributed in Connecticut, Delaware, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Virginia, Vermont, and West Virginia.

Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101.

This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 1, 1991.

Dated: March 22, 1991.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91–7559 Filed 3–29–91; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 91M–00113]

Sola/Barnes-Hind; Premarket Approval of Fluorocon™ (Paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Sola/Barnes-Hind, Sunnyvale, CA, for permarket approval, under the Medical Device Amendments of 1976, of the spherical Fluorocon ™ (paflufocon B) Rigid Gas Premeable Contact Lenses for Daily and Extended Wear (Clear and Tinted). The lenses are

to be manufactured under an agreement with Paragon Optical, Mesa, AZ, which has authorized Sola/Barnes-Hind to incorporate information contained in its approved premarket approval application and related supplement for the FluoroPerm ™ (paflufocon A) Rigid Gas Permeable Contact Lenses for Daily Wear and FluoroPerm® 60 (paflufocon B) Rigid Gas permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 28, 1990, of the approval of the application.

DATES: Petitions for administrative review by May 1, 1991.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 1390 Piccard Drive, Rockville, MD 20850, 301–427–1080.

SUPPLEMENTARY INFORMATION: On September 29, 1989, Sola/Barnes-Hind, Sunnyvale, CA 94086–5200, submitted to CDRH a supplemental application for premarket approval of the spherical Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted). The Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses (Clear and Tinted) are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lenses are indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes who are myopic or hyperoic and may have corneal astigmatism of 4.00 diopters (D) or less that does not interfere with visual acuity. The daily wear lenses range in powers from −20.00 D to +12.00 D and the extended wear lenses range in powers from −20.00 D to +8.00 D. These lenses are to be disinfected using a chemical lens care system. The lenses are available in untinted (clear), blue, or green tints. The tinted lenses contain one or both of the color additives, D&C Green No. 6 and D&C Yellow No. 10, in accordance with the color additive listing provisions of 21 CFR 74.3206 and 74.3710. The application includes authorization from Paragon Optical of Mesa, AZ 85204, to incorporate information contained in its approved premarket approval application and related supplement for the Fluoroperm™ (paflufocon A) Rigid Gas Permeable Contact Lenses for Daily Wear and FluoroPerm® 60 (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted).

On December 28, 1990, CDRH approved the application by letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above. The labeling of the Fluorocon™ (paflufocon B) Rigid Gas Permeable Contact Lenses for Daily and Extended Wear (Clear and Tinted) states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review, to be used, the persons who may participate in the review, the time and place where the review will occur, and othe details.

Petitioners may, at any time on or before (May 1, 1991, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 22, 1991.

Elizabeht D. Jacobson,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. 91–7515 Filed 3–29–91; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 91M–0089]

Vision Technologies International; Premarket Approval of Models A21–A and A21–B Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Vision Technologies International, San Dimas, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Models, A21–A and A21–B Ultraviolet-Absorbing Posterior Chamber Intraocular Lenses (IOL's). The IOL's are to be manufactured under an agreement with Newlensco, Monrovia, CA, which has authorized Vision Technologies International to incorporate information contained in its approved premarket approval application for the Newlensco UV Classic Series™ Posterior Chamber IOL's. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 28, 1991, of the approval of the application.

DATES: Petitions for administrative review by May 1, 1990.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food